

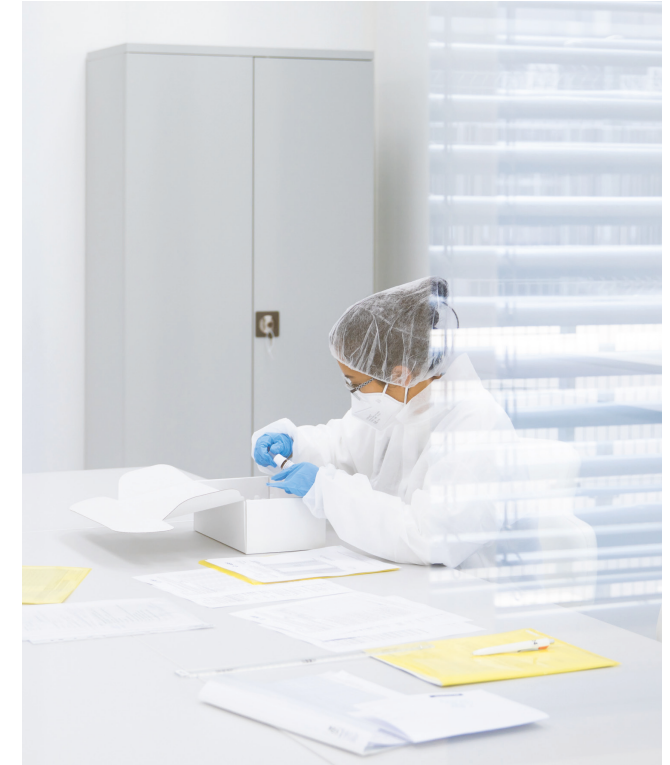
About the GBA Group

GBA Group is an international life science service company with more than 2,000 employees and a broad range of analytical, logistical and specialist services in the fields of pharmaceuticals, medical products, cosmetics, chemicals, food, drinking water and the environmental sustainability.

The range of services offered by the GBA Group includes laboratory analytics, data management, special logistical services for clinical trials, as well as consulting services for private companies and public institutions in connection with their activities in the fields of research, product development, market development, and consumer protection.

Through its work, the GBA Group makes a sustainable contribution to public health, the environment and society as a whole.

The GBA Group operates sites in Austria, Belgium, Finland, France, Germany, Poland, Spain, and the United States.



ABF - Clinical Trial Supply

CONTACT:

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GBA-GROUP.COM/EN/ABF



Clinical Trial Supply Services

- Import/Export and Customs Clearance
- GMP Storage of IMP, GMO and API at a Variety of Temperature Ranges 15-25 °C, 2-8 °C, -20°C, -80 °C, -150°C, LN2
- Controlled Drug Substances Handling
- Qualified GDP Transport (all Temperature Ranges)
- Project & Quality Management
- GMP certified service provider
- Comparator Sourcing
- Return Supplies, Reconciliation, Storage and Destruction
- Distribution & Depot Services

Labeling and Packaging

- Label Text Translation and Verification
- Label Design and In-House Printing
- Labeling and Cold Chain Labeling
- Lab/Patient Kit Labeling and Assembly
- Customized Primary and Secondary Packaging

QP Release

- QP Release and Regulatory Consultancy Services
- GMP & GDP Audit Services

PBMC

- PBMC Isolation Lab Network



Support of International Clinical Studies

ABF is a GMP-certified company with a wide range of pharmaceutical services for investigational medicinal products and approved drugs: Our services range from primary and secondary packaging including kit production and labeling, to storage and distribution at a wide range of temperatures. We take care of your product all the way through certification and release by our Qualified Persons (QPs). In addition, ABF has also established a qualified laboratory network to ensure high quality isolations of Peripheral Blood Mononuclear Cells (PBMCs).

An Experienced Team

Our dedicated team has extensive expertise in managing complex clinical trials. The ABF logistics team uses qualified couriers with full tracking systems to transport temperature sensitive investigational clinical products correctly and on time.

Logistics Experts at the Heart of Europe

With our headquarters at the heart of Europe - Vienna, Austria - we can offer fast, and efficient service solutions for all pharmaceutical products. ABF is a reliable partner for leading pharmaceutical and biotechnology companies worldwide. We operate internationally - mainly in Europe, the USA and Asia - and are continuously expanding our distribution network.

Our quality standards meet the highest pharmaceutical demands.

Fields of Expertise

Preclinical Services

- In-Vitro ADME
- In-Vitro DMPK Studies
- GLP / Non-GLP Bioanalysis

Phone +49 681 3946 - 7510
info@pharmacelsus.com

- GCLP Bioanalysis
- Services for Biologics
- Biomarker Services

Hepatocytes and Toxicology

- In-Vitro screening for CYP induction
- In-Vitro regulatory (FDA/EMA) CYP and UGT induction
- In-Vitro metabolic Stability & Metabolite Identification
- In-Vitro and Ex-Vitro Acute and Chronic Liver-related Toxicities

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Zylan.lr@kaly-cell.com
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- In-Vitro and Ex-Vitro Drug induced liver injury
- In-Vitro assays for evaluation of direct effects on thyroid (TPO, DEIO, NIS)

Clinical Trial Supply

- Labeling & Packaging
- GMP Storage & Global Distribution
- Import & Export
- Storage at 15-25 °C, 2-8 °C, -20 °C, -80 °C, -150 °C, LN2
- CTM and Commercial Services

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- QP Release & QP Services
- Audit Services
- Quality Management
- Sourcing
- Controlled Substances
- PBMC Network

Central Laboratory

- Safety Analysis
- Bioanalysis
- Lab Kit Supply
- Worldwide Logistics

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- Specimen Storage
- Data Management
- Quality Assurance Service

GMP Testing

- Research Development Analysis
- Method Development & Validation
- Quality Control
- EU-Retesting
- Particles and Particles Size Distribution
- Microbiology
- Stability Testing & Storage
- Packaging Material Testing

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- Extractables & Leachables Studies
- Elemental Impurities (ICH Guideline Q3D)
- Amino Acid Analysis (ninhydrin-positiv substances)
- PCR
- Regulatory Affairs Services, e.g. eCTD Services incl. Submissions

Medical Devices

- Qualification of biocompatibility of devices/materials
- Qualification and monitoring of manufacturing hygiene, product cleaning/cleanliness, packaging procedures/packaging systems and sterilization procedures

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- Validation of processing (reusability)
- Seminars / Trainings